

## REMARKS

Claims 1-17 and 113-124 constitute the pending claims in the present application. Claims 10 and 17 have been canceled without prejudice. Claims 1, 11, 12, 113, and 125 have been amended. Claim 1, as amended, recites the elements of claim 10, now cancelled. These amendments serve to expedite prosecution of the application and to further define a preferred embodiment of the claimed invention, but are not meant to limit the scope of the present invention. Applicants reserve the right to pursue claims of similar or differing scopes in future applications.

No new subject matter has been added, and the amended claims should not necessitate an additional search. Support for the amended claims can be found in the application and claims as originally filed. Support for those amendments that cannot be found directly in the claims as filed can be found in the specification. For example, support for the amendments to the claims regarding providing a system comprising “one or more passive detection elements” can be found in the application on page 11, lines 19-22 and in the examples (see e.g., pages 28-30) and figures (see e.g., Figures 1.4 and 2.1).

The issues raised by the Examiner in the outstanding Office Action are addressed below in the order they appear in the prior Action.

### The Claims Comply with 35 U.S.C. §112

#### Rejection of Claims 1-17 and 113-133 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph

Claims 1-17 and 113-133 are rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention.

In particular, the Examiner has rejected Claims 1 and 129-133 as vague and indefinite because “it is unclear how the transient electrical signal giving rise to a decaying waveform is generated and controlled”. The Examiner contends that “it is not entirely clear whether the transient electrical signal giving rise to a decaying waveform is

intentional, and if so, it is unclear what the steps are that would teach how the transient electrical signal...would be generated and controlled”. Claim 1 has been amended to recite that “the transient electrical signal gives rise to a decaying waveform and is caused by a monodirectional movement of said first molecule X through said conducting medium sample relative to said immobilized second molecule Y”. Applicants have amended Claim 1 to further clarify and define a preferred embodiment of the claimed invention whereby the transient electrical signal thus generated is then measured. In particular, Claim 1, as amended, recites that the immobilized second molecule Y is “immobilized on a surface of a first working electrode and wherein said first working electrode is a passive detection element” and that the “transient electrical signal is measured using said first working electrode”.

Applicants respectfully point out that, in determining the definiteness, the language of a claim must be analyzed, not in a vacuum, but in light of: (i) the content of the particular application disclosure, and (ii) the teachings of the prior art, and (iii) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. See, for example, *In re Marosi*, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983).

Following this analysis, Applicants point out that, as to the first factor to be considered, the specification is replete with explanations and examples of the intended scope of these terms. The Examiner’s attention is drawn to pages 8-9 of the specification, beginning with the first full paragraph on page 8. This section teaches that the transient electrical signal is generated by the movement of the first molecule relative to the second molecule through the conducting medium. Additionally, pages 9-11 teach the use of electrodes in the detection of the transient electrical signal generated by the movement of molecule X relative to molecule Y. Furthermore, as to the second factor to be considered, Applicants submit that the teachings of the prior art provide guidance to the skilled artisan in interpreting the scope of modifications claimed. Finally, as to the final factor to be considered, Applicants note that one of ordinary skill in the art at the time the invention was made would have no difficulty in determining the metes and bounds of the claimed subject matter.

The Examiner rejects Claim 17 as vague and indefinite because “it is unclear what is actually being measured”. In light of Applicants’ cancellation of claim 17, this rejection has been rendered moot.

Applicants believe the aforementioned amendments and the preceding discussion obviate the Examiner’s rejection of claims 1-17 and 113-133 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

The Claims Comply with 35 U.S.C. §102

Rejection of Claims 1-3, 5, 7, and 10-13 under 35 U.S.C. 102(b) [Park et al In vivo nitric oxide sensor using non-conducting polymer-modified carbon fiber (1998) Biosensors & Bioelectronics 13:1187-1195]

Claims 1-3, 5, 7, and 10-13 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Park et al. Applicants traverse this rejection to the extent it is maintained over the claims as amended.

The standard for anticipation is that “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claim 1 as amended recites providing a system comprising one or more *passive detection elements*, an immobilized second molecule Y, a conducting medium sample, and a first molecule X, wherein said immobilized second molecule Y is immobilized on a surface of a first working electrode and wherein *said first working electrode is a passive detection element*; detecting a transient electrical signal, wherein the transient electrical signal gives rise to a decaying waveform and is caused by a monodirectional movement of a first molecule X through a conducting medium sample relative to an immobilized second molecule Y, wherein the transient electrical signal *is measured using the first working electrode*; and relating said detected transient electrical signal to at least one

characterizing feature of said first molecule X and said second molecule Y. [Emphasis added].

Park et al. do not disclose detecting a transient electrical signal as recited in the pending claims. Detection of a signal in the Park et al. disclosure requires active detection elements, namely an externally applied electrical stimulus, such as a potential applied to the working electrode (see e.g., p. 1189, first paragraph). This is in contrast to the amended claims that recite detecting a transient electrical signal that is measured using a first working electrode, “wherein said first working electrode is a passive detection element”. Park et al. fail to teach or suggest the use of passive detection elements to detect a transient electrical signal, such as the use of the first working electrode recited in the pending claims.

Claims 2-3, 5, 7, and 10-13 are dependent on claim 1. As discussed above, claim 1 is not anticipated by Park et al. Because a dependent claim incorporates every element of the independent claim from which it depends, the dependent claims of claim 1 are thus not anticipated by Park et al. Accordingly, Applicants submit that Park et al. do not anticipate the pending claims. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 1-5, 7, 9-14, 113, 117, 119-121, 123-125, 127, and 129 under 35 U.S.C. 102(e) (Wang et al US 6,468,785)

Claims 1-5, 7, 9-14, 113, 117, 119-121, 123-125, 127, and 129 are rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Wang et al (US 6,468,785). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

Claims 1 and 125 as amended recite, in part, detecting a transient electrical signal using a first working electrode, wherein the first working electrode is a *passive detection element*.

Wang et al. do not disclose detecting a transient electrical signal as recited in the pending claims. Wang et al. require active detection elements, namely an externally applied electrical stimulus, such as a potential applied to the working electrode (see e.g., column 8, lines 53-54, and column 12, lines 20-27), in order to detect DNA hybridization. In contrast, the pending claims recite detecting a transient electrical signal that is measured using a first working electrode, “wherein said first working electrode is a passive detection element”. Wang et al. fail to teach or suggest detecting a transient electrical signal by using a passive detection element to measure the signal.

In addition, claims 2-5, 7, 9-14, 113, 117, 119-121, 123-124, 127, and 129 are dependent on either claim 1 or claim 125. As argued above, claim 1 and claim 125 are not anticipated by Wang et al. Because a dependent claim incorporates every element of the independent claim from which it depends, the respective dependent claims of claims 1 and 125 are thus not anticipated by Wang et al. Accordingly, Applicants submit that Wang et al. do not anticipate the pending claims. Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection of Claims 1, 7-13, and 15 under 35 U.S.C. 102(b) (Yacynych US 5,540,828)

Claims 1, 7-13, and 15 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Yacynych (US 5,540,828). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

At most, Yacynych discloses amperometric detection of an analyte, which requires an active detection element, such as an electrode to which an electric current has been applied (see e.g., the abstract). In contrast, claim 1 recites detecting a transient electrical signal that is measured using a first working electrode, “wherein said first working electrode is a passive detection element”. Yacynych fails to teach or suggest this element recited in the pending claims.

In addition, claims 7-13 and 15 are dependent on claim 1. As discussed above, claim 1 is not anticipated by Yacynych. Because a dependent claim incorporates every element of the independent claim from which it depends, the respective dependent claims of claim 1 are thus not anticipated by Yacynych. Accordingly, Applicants submit that Yacynych does not anticipate the pending claims. Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection of Claims 1-3, 6-8, 10-15, 113-118, and 125-128 under 35 U.S.C. 102(b) (Saini et al US 5,521,101)

Claims 1-3, 6-8, 10-15, 113-118, and 125-128 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Saini et al. (US 5,521,101). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

At most, Saini et al. disclose electrochemical detection of an analyte in a method that requires an active detection element, namely an externally applied electrical stimulus, such as an applied potential (see e.g., column 10, Example 1). In contrast, claims 1 and 125 recite detecting a transient electrical signal that is measured using a first working electrode, “wherein said first working electrode is a passive detection element”. Saini et al. fails to teach or suggest this element recited in the pending claims.

In addition, claims 2-3, 6-8, 10-15, 113-118, and 126-128 are dependent on either claims 1 or 125. As argued above, claim 1 and claim 125 are not anticipated by Saini et al. Because a dependent claim incorporates every element of the independent claim from which it depends, the respective dependent claims of claims 1 and 125 are thus not anticipated by Saini et al. Accordingly, Applicants submit that Saini et al. do not anticipate the pending claims. Applicants respectfully request reconsideration and withdrawal of this rejection.

For the reasons stated above, Applicants submit that the claimed invention is not anticipated by the cited references. Applicants submit that none of the cited references teach or suggest the use of one or more passive detection elements to detect a transient electrical signal. Accordingly, Applicants respectfully request reconsideration and withdrawal of the §102 rejections.

Rejection of Claim 122 under 35 U.S.C. 103(a) [Wang et al (US 6,468,785) in view of Henkens et al (US 6,391,558)]

Claim 122 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Wang et al. (US 6,468,785) in view of Henkens et al. (US 6,391,558). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

The Examiner's attention is drawn to MPEP § 706.02(j), which sets forth that a teaching or suggestion provided by the prior art reference (or references when combined) of all the claimed limitations is necessary to establish a *prima facie* case of obviousness. The following comments address this requirement of a rejection under 35 U.S.C. § 103(a).

Wang et al. is discussed above. Henkens et al. disclose an electrochemical detection system in which a biochemical reaction generates a measurable current when an external electrical stimulus is applied, namely, when an amperometric potential is applied. Neither Wang et al. nor Henkens et al., either alone or in combination, teach or suggest detecting a transient electrical signal that is measured using a first working electrode, "wherein said first working electrode is a passive detection element", as is recited in the pending claims.

For the foregoing reasons, Applicants believe that the references cited by the Examiner do not render the claimed subject matter *prima facie* obvious under 35 U.S.C § 103(a). Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

## CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the pending claims are in condition for allowance, and early and favorable reconsideration is respectfully solicited.

If there are any other fees due in connection with the filing of this Response, please charge the fees to our **Deposit Account No. 18-1945** under Order No. SUPP-P01-012.

Respectfully submitted,

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